

HUMAN SERVICES BOARD

INTRODUCTION

FINDINGS OF FACT

3. In a decision dated November 30, 2004, the request was denied because the petitioner had not shown that she had a unique medical condition or would suffer detrimental health consequences without the cod liver oil. DCF/ESD advised the petitioner that it covered a number of medications for mood

disorder and that the efficacy of cod liver oil for this purpose had not been proven.

4. The petitioner filed an appeal on January 10, 2005. The petitioner was advised during a status conference on this appeal to obtain additional evidence addressing the concerns of DCF/ESD and to submit it for further review.

5. The petitioner submitted additional evidence on March 28, 2005 from her treating psychiatrist which included his opinion, supported by attached studies reported in a psychiatric journal, that omega-3 fatty acids found in fish oils were successfully treating mood disorders. It was his opinion that fish oils would be efficacious for the petitioner and would avoid side-effects she was experiencing from traditional synthetic mood stabilizers.

6. On May 11, 2005, DCF/ESD reversed its original decision and determined that it would make an exception for the petitioner and cover cod liver oil as a mood stabilizer. It provided the petitioner with a list of seventeen brands of fish oils which it would pay for under rebate agreements with the manufacturers.

7. The matter was not settled at that time, however, because the petitioner insisted on the provision of a certain type of cod liver oil, "Carlson's Norwegian" which was not on

the list. It was the petitioner's understanding that this brand was the only one that had quality control processes in place to minimize the occurrence of mercury in the product. She also had problems with the low doses found in many of the oil supplements which would necessitate taking large quantities of the medication each day.

8. DCF/ESD denied the request to cover the Carlson's brand because it did not have a rebate contract with that manufacturer. Instead, it suggested to the petitioner that she try "Spectrum Norwegian" cod liver oil as it was available in more concentrated doses and was similar, in the Department's view to the "Carlson's Norwegian".

9. The petitioner agreed to try that brand and it appeared in late June of 2005 that the matter might finally be settled. However, issues arose between the parties about the ability of the petitioner's local pharmacy to obtain Spectrum and about whether the Spectrum provided by that pharmacy was actually the one discussed by DCF/ESD or was, in fact, another compounding fish oil made by a manufacturer with a similar name.

10. The petitioner ultimately determined that she did not feel that any cod liver oil but the Carlson's was safe enough for her use and in July of 2005 asked for the matter

to be reset for hearing on the brand name issue. The petitioner was unable to participate in a subsequently scheduled hearing due to a flare up in and hospitalization for her multiple sclerosis. However, she obtained letters of support from the neurologists treating her multiple sclerosis dated September 18 and November 10, 2005. The November 10 letter said much the same as the September 18 letter and is set out below:

This particular formulation (Carlson's Norwegian Cod Liver Oil) is rigorously tested at regular intervals and certified to be free of elemental Mercury and Mercury compounds. Although no causal link has been established between Mercury exposure and MS pathogenesis, it is well accepted that Mercury exposure is harmful in general and is related to the development and exacerbation of neurological disorders. For this reason, we feel that it would be unsafe for her to take other Omega-3 products that are not as rigorously tested, and continue to recommend that this be covered for her use.

11. On November 30, 2005, DCF/EDS responded that the petitioner's physicians had assumed that other fish oils on their coverage list were not as rigorously tested as Carlson's and continued to deny the request. The hearing officer responded on December 12, 2005 that if the Department was maintaining that some of their covered fish oils were, in fact, as rigorously tested as Carlson's for the presence of mercury, that DCF/ESD should present admissible evidence of

that fact by December 31, 2005. DCF/ESD asked for and received an extension to January 6 to present that evidence.

12. On January 9, 2005, DCF/EDS presented a letter from its medical director assuring the petitioner that the Spectrum oil it covered at her pharmacy was the one similar to Carlson's and that it would work with her pharmacy to make sure she could regularly obtain it.¹ The medical director stated that Spectrum and Carlson's were processed in the same way using the same kind of fish, caught in the same locations, in the same manner. He added that both had been rated under a number of standards by environmental and trade organizations and that Spectrum was found to have contaminant control for mercury (and other substances) at least equal to if not better than that of Carlson's. The medical director noted that Spectrum was categorized as a "Best Choice" in one survey and that Carlson's rating in that same survey was incomplete because of the failure of the company to supply sufficient information. The director declined to make an M108 exception for the provision of Carlson's fish oil because he felt DCF/ESD could supply a cod liver oil

¹ At the time this case came before the Board, the petitioner claimed that the coverage code (NDC 49452220001) was producing a compounding strength spectrum rather than the one described herein. The Department promised to contact the pharmacy involved to clear up the error.

preparation equal to or better than that requested by the petitioner. In addition, the medical director felt the petitioner had failed to show that she would suffer a detrimental health consequence if the exception were not granted for the brand she wanted.

13. Documents supporting the medical director's opinion were as follows:

(a) On-line descriptions from both Spectrum's and Carlson's websites claiming extraction of fish oil through non-chemical methods from line-caught fish in deep waters off Norway. Analyses of the contents of both oils showed roughly similar high concentrations of DHA and EPA per liquid teaspoon of fish oil and included claims by both that the oil's purity was tested to ensure that mercury levels were "below acceptable limits" (Spectrum) and "free of detectable levels" (Carlson's).

(b) A survey conducted by "Environmental Defense" contained on the "Oceans Alive" website which asked dozens of fish oil manufacturers whether they purified their products to rid them of mercury and other contaminants; what methods they used; and what standards were used to judge their purity. Those conducting the survey ranked the FDA standards as lowest and those used by California, the EPA, and a trade association called the "Council for Responsible Nutrition" as the strictest. The survey concluded that most fish oil manufacturers in the survey produced oils which met the strictest standards for purity and rated those oils as a "Best Choice". Included in that list were Spectrum and two other fish oils (out of the seventeen) covered under the Medicaid program. Geltabs, salmon oil, and "Very Finest Fish Oil" produced by Carlson's were also included on the "Best Choice" list, but not Carlson's liquid fish oil (the type used by the petitioner) because information provided by the company was deemed "incomplete".

14. The petitioner has not responded to DCF/ESD's submission, although thirty days have passed. The detailed evidence offered by DCF/ESD on the purity of Spectrum is uncontradicted by reliable evidence in the record. Therefore, DCF/ESD's assertion that Spectrum oil is also rigorously tested to control mercury contamination is found as fact herein.

ORDER

The decision of DCF/ESD denying payment for Carlson's fish oil products is affirmed.

REASONS

DCF/ESD's regulations will not cover vitamins and minerals unless they are specified for a specific disease. M811.3. The petitioner was apparently denied the provision of omega-3-fatty acids under this provision based on DCF/ESD's belief that this substance was an unconventional and unproven method to deal with the petitioner's mood substances and that other traditional remedies were available to the petitioner which were covered by Medicaid. The petitioner then filed a request for payment of a substance not included on a list of covered services and items under

M108 of DCF/ESD's regulations. Her request initially met with the same response, denial. After the introduction of new evidence, including the opinion of her treating psychiatrist that this was an efficacious method of mood stabilization for the petitioner and was superior to traditional remedies due to her side-effect issues, DCF/ESD reversed its decision and agreed to pay for cod liver oil as a treatment for her mood disorder. That issue is settled and is no longer before the Board.

What remains is the petitioner's contention that DCF/ESD has acted arbitrarily under the M108 procedures in refusing to cover a specific brand item of cod liver oil. Under the M108 procedures, DCF/ESD is required to consider, among other factors, whether there "are extenuating circumstances unique to the beneficiary such that there would be serious detrimental health consequences if the service were not provided." M108(1). DCF/ESD must also consider whether the request falls into the category of "less expensive, medically appropriate alternatives" to products covered in the regulations. M108(8). As DCF/ESD has presented persuasive evidence that its covered cod liver oil (Spectrum) is as rigorously tested for mercury contamination as that the petitioner wishes to use, DCF/ESD correctly determined that

the petitioner would suffer "no detrimental health consequences" if the Carlson's was not provided. In addition, DCF/ESD's decision to cover the cheaper (due to rebates), equally pure Spectrum fulfills the expectation in the regulations that the "less expensive, medically appropriate" alternative be utilized as a cost control measure. As DCF/ESD's decision is in accord with its regulation, the Board is bound to uphold the result. 3 V.S.A. § 3091(d), Fair Hearing Rule 17.

#